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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,495	11/13/2000	Bruce Joseph Roser	P65952US0	9084

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EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

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DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/623,495

Applicant(s)

ROSER ET AL.

Examin r

Michael C. Henry

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 recites the phrase, " at least one compound having an activity that is about 80% or more of its original activity ", in lines 3 and 4 of the claim. However, this phrase renders the claim indefinite and confusing, since it is unclear as to what kind of activity is being referred to in the claim. In addition, the phrase "original activity" renders the claim indefinite since it is unclear as to what point is the said activity considered original. Furthermore, the phrase "80% or more" is indefinite, since the word "more" implies that there is no upper limit to the percentage activity value (i.e. more implies that the % activity value can be extremely greater than 100). Thus, because of the indefiniteness of claim 45, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-28, 33, 37-44, 46-50 and 55 rejected under 35 U.S.C. 102(b) as being anticipated by Foster et al. (US 6,258,341 B1).

In claim 21, applicants' claim "a method for making a composition comprising amorphous sugar glass without crystals therein and at least one compound having an activity that is about 80% or more of its original activity after a period of time at about 37 °C to about 70 °C which comprises (a) forming an aqueous system which is a solution of (i) one or more monosaccharide sugar alcohol which would normally form sugar crystals on drying; (ii) a compound which is normally subject to deactivation on drying, or a mixture of such compounds; and (iii) at least one additive which is a glass-former or a formulation-facilitator, the total amount of the additive being sufficient to cause the monosaccharide sugar alcohol to form a glass on drying; wherein the additive itself does not crystallize during the drying step (b); (b) drying the aqueous system; and (c) solidifying the component (i), (ii) and (iii) as an amorphous glass without crystals therein, whereby the amorphous glass stabilizes the compound or mixture of compounds therein and prevent damage thereto during drying." Foster et al. disclose a method for making a composition comprising amorphous sugar glass without crystals therein and at least one compound having an activity which comprises (a) forming an aqueous system which is a solution of (i) one monosaccharide sugar alcohol (mannitol) which would normally form sugar crystals on drying; (ii) a compound which is normally subject to deactivation on drying (Human zinc insulin); and (iii) at least one additive (sodium citrate) which is a glass-former or a formulation-facilitator, the total amount of the additive being sufficient to cause the monosaccharide sugar alcohol to form a glass on drying; wherein the additive itself does not crystallize during the drying step (b); (b) drying the aqueous system; and (c) solidifying the

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components (i), (ii) and (iii) as an amorphous glass without crystals therein, whereby the amorphous glass stabilizes the compound therein and prevent damage thereto during drying (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20). Claims 22-28, 33 are also rejected because, the limitations and/or dependability encompassed by these claims are also anticipated by Foster et al. (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20). It should be noted that the examiner affords very little weight to the preamble of the claim which recites, “and at least one compound having an activity that is about 80% or more of its original activity after a period of time at about 37 °C to about 70 °C”, since the claim is a method claim, and said activity of the compound after a period of time and at particular temperature ranges would depend on the specific compound used and other conditions, factors or variables that are extraneous to the method of preparation like the pressure, type of atmosphere exposure (e.g. humidity conditions), and the container in which the composition is stored for said period. In fact, the said activity of the compound after a period of time also depends on the nature of the compound which includes the chemical and physical characteristics of the compound. Thus, applicant’s claim of special percentage ranges for the compound’s activity does not further limit the claim. Therefore, claims 37-44 which are drawn to the method of claim 21, involving compounds of specific percent activity and specific time periods, are also encompassed by this rejection.

In Claim 45, applicant claims “a composition comprising an amorphous sugar glass without crystals therein containing at least one monosaccharide sugar alcohol and at least one additive which is a glass-former or a glass-formation-facilitator and at least a compound having

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an activity that is about 80% or more of its original activity after a period of storage at about 37 °C to about 70 °C in a weight ratio of the monosaccharide sugar alcohol plus the additive to the compound of at least 0.25:1” Foster et al. disclose applicant’s composition comprising an amorphous sugar glass without crystals therein containing at least one monosaccharide sugar alcohol (mannitol) and at least one additive (sodium citrate) which is a glass-former or a glass-formation-facilitator and at least a compound (Human zinc insulin) having pharmacological activity in a weight ratio of the monosaccharide sugar alcohol plus the additive to the compound of at least 0.25:1 (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20). It should be noted that the examiner gives very little weight to the language pertaining to the percentage of the original activity and to the period of storage at particular temperatures, since the indefiniteness of this language or phrase does not further limit the claim (see also, the 112 rejection stated above). In fact, Foster et al. composition may well have said activity under said conditions. Claims 46-50, 55 which are drawn to specific ratio of sugar alcohol plus the additive to the compound, specific compounds, specific conditions of drying and specific sugar alcohols, are also rejected because, the limitations and/or dependability encompassed by these claims are also anticipated by Foster et al. (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster et al. (US Patent No. 6,258,341 B1).

In claim 21, applicants' claim "a method for making a composition comprising amorphous sugar glass without crystals therein and at least one compound having an activity that is about 80% or more of its original activity after a period of time at about 37 °C to about 70 °C which comprises (a) forming an aqueous system which is a solution of (i) one or more monosaccharide sugar alcohol which would normally form sugar crystals on drying; (ii) a compound which is normally subject to deactivation on drying, or a mixture of such compounds; and (iii) at least one additive which is a glass-former or a formulation-facilitator, the total amount of the additive being sufficient to cause the monosaccharide sugar alcohol to form a glass on drying; wherein the additive itself does not crystallize during the drying step (b); (b) drying the aqueous system; and (c) solidifying the component (i), (ii) and (iii) as an amorphous glass without crystals therein, whereby the amorphous glass stabilizes the compound or mixture of compounds therein and prevent damage thereto during drying." Claims 29-32, 34 and 35, are further limitations of claim 21 which are drawn to a method or product pertaining to specific additives or monosaccharide alcohols. ."

Foster et al. disclose a method for making a composition comprising amorphous sugar glass without crystals therein and at least one compound having an activity which comprises (a) forming an aqueous system which is a solution of (i) one monosaccharide sugar alcohol (mannitol) which would normally form sugar crystals on drying; (ii) a compound which is normally subject to deactivation on drying (Human zinc insulin); and (iii) at least one additive

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(sodium citrate) which is a glass-former or a formulation-facilitator, the total amount of the additive being sufficient to cause the monosaccharide sugar alcohol to form a glass on drying; wherein the additive itself does not crystallize during the drying step (b); (b) drying the aqueous system; and (c) solidifying the components (i), (ii) and (iii) as an amorphous glass without crystals therein, whereby the amorphous glass stabilizes the compound therein and prevent damage thereto during drying (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20). In addition, Foster et al. disclose a method and product of elcatonin powder prepared from elcatonin and glass formers and additives (example 18, col. 43).

The difference between applicants claimed method and the method that is exemplified by Foster et al. is that, Foster et al. do not disclose the identical glass formers or additives like those claimed by the applicants'. However, Foster et al. suggest that additives used by the applicants including, peptides, proteins, and salts like calcium lactate, sodium tetraborate can be used (col. 12, lines 25-37), (col. 13, lines 13-20), (col. 12, line 65 to col. 13, line 12). Foster et al. also suggest that monosaccharide sugar alcohols other than mannitol (like xylitol and sorbitol) can be used (col. 11, lines 24-36).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use the method of drying of Foster et al. to prepare a composition comprising an amorphous glass, without crystals therein, of compounds using different monosaccharide sugar alcohols and additives.

One having ordinary skill in the art would have been motivated, in view of Foster et al., to prepare amorphous glass, without crystals therein, of compounds using different



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monosaccharide sugar alcohols and additives, depending on cost, availability and/or convenience of use. The preparations of different amorphous glass compositions are well known in the art.

In claim 36, applicants claim “The composition of claim 21 wherein the amorphous glass comprises: ..... ; Mannitol 50%, and dextran 50%.;.....”

Foster et al. disclose a composition of claim 21 consisting of mannitol and other additives (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20).

The difference between applicants claimed composition and the composition that is exemplified by Foster et al. is that, Foster et al. do not disclose the use of dextran in combination with mannitol. However, Foster et al. suggest that dextran is a glass former (see table 1, col. 14, lines 49-65). In addition, Foster et al. use more than one additive in his method.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to use the method of drying of Foster et al. to prepare a composition comprising an amorphous glass of compounds using different monosaccharide sugar alcohols and/or additives in different percent combinations.

One having ordinary skill in the art would have been motivated, to use the method of drying of Foster et al. to prepare a composition comprising an amorphous glass of compounds using different monosaccharide sugar alcohols and/or additives in different percent combinations, depending on cost, availability and/or convenience of use. The preparations of different amorphous glass compositions are well known in the art.

In Claim 45, applicant claims “a composition comprising an amorphous sugar glass without crystals therein containing at least one monosaccharide sugar alcohol and at least one

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additive which is a glass-former or a glass-formation-facilitator and at least a compound having an activity that is about 80% or more of its original activity after a period of storage at about 37 °C to about 70 °C in a weight ratio of the monosaccharide sugar alcohol plus the additive to the compound of at least 0.25:1” Claims 51-57 which are further limitations of claim 45 are drawn to the composition containing specific additives, specific sugar alcohols and specific compounds.

Foster et al. disclose applicant’s composition comprising an amorphous sugar glass without crystals therein containing at least one monosaccharide sugar alcohol (mannitol) and at least one additive (sodium citrate) which is a glass-former or a glass-formation-facilitator and at least a compound (Human zinc insulin) having pharmacological activity in a weight ratio of the monosaccharide sugar alcohol plus the additive to the compound of at least 0.25:1 (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20). In addition, Foster et al. disclose a product of elcatonin powder prepared from elcatonin and glass formers and additives (example 18, col. 43).

The difference between applicants claimed composition and the composition that is exemplified by Foster et al. is that, Foster et al. do not disclose the identical glass formers or additives like those claimed by the applicants’. However, Foster et al. suggest that additives used by the applicants including, peptides, proteins, and salts like calcium lactate, sodium tetraborate can be used (col. 12, lines 25-37), (col. 13, lines 13-20), (col. 12, line 65 to col. 13, line 12). Foster et al. also suggest that monosaccharide sugar alcohols other than mannitol (like xylitol and sorbitol) can be used (col. 11, lines 24-36).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared Foster et al. composition comprising an amorphous glass,

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without crystals therein, of compounds using different monosaccharide sugar alcohols and additives.

One having ordinary skill in the art would have been motivated, in view of Foster et al., to prepare Foster et al. composition comprising an amorphous glass, without crystals therein, of compounds using different monosaccharide sugar alcohols and additives, depending on cost, availability and/or convenience of use. It should be noted that claims 59-66 which are drawn to the composition of claim 45, involving compounds of specific percent activity and specific time periods, are also encompassed by this rejection, since that the examiner gives very little weight to the language pertaining to the percentage of the original activity and to the period of storage at particular temperatures, since the indefiniteness of this language or phrase does not further limit the claim (see also, the 112 rejection stated above). In fact, Foster et al. composition may well have said activity under said conditions.

In claim 58, applicants claim "The composition of claim 45 wherein the amorphous glass comprises: ..... ; Mannitol 50%, and dextran 50%;....."

Foster et al. disclose a composition consisting of mannitol and other additives (example 3, col. 23; see also, table 1, col. 14, lines 49-65; see also example 1, col. 18 and example 2, col. 20).

The difference between applicants claimed composition and the composition that is exemplified by Foster et al. is that, Foster et al. do not disclose the use of dextran in combination with mannitol. However, Foster et al. suggest that dextran is a glass former (see table 1, col. 14, lines 49-65). In addition, Foster et al. use more than one additive in his method.

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It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared Foster et al. composition comprising an amorphous glass, without crystals therein, of compounds using different monosaccharide sugar alcohols and/or additives in different percent combinations.

One having ordinary skill in the art would have been motivated, in view of Foster et al. to prepare Foster et al. composition comprising an amorphous glass, without crystals therein, of compounds using different monosaccharide sugar alcohols and/or additives in different percent combinations, depending on cost, availability and/or convenience of use. The preparations of different amorphous glass compositions are well known in the art.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 703 308-7307. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703 308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

May 8, 2003.

  
SAMUEL BARTS  
PRIMARY EXAMINER  
GROUP 1600

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